

IC 35-48-7

Chapter 7. Central Repository for Controlled Substances Data

IC 35-48-7-1

Repealed

(Repealed by P.L.84-2010, SEC.102.)

IC 35-48-7-2

Repealed

(Repealed by P.L.65-2006, SEC.18.)

IC 35-48-7-2.9

"Dispense" defined

Sec. 2.9. (a) As used in this chapter, "dispense" has the meaning set forth in IC 35-48-1-12.

(b) The term does not apply to the following:

- (1) A drug administered directly to a patient.
- (2) A drug dispensed by a practitioner, if the quantity dispensed is not more than a seventy-two (72) hour supply of a controlled substance listed in schedule II, III, IV, or V as set forth in IC 35-48-3-9.

As added by P.L.105-2008, SEC.65.

IC 35-48-7-3

Repealed

(Repealed by P.L.105-2008, SEC.66.)

IC 35-48-7-4

"Exception report"

Sec. 4. As used in this chapter, "exception report" means a record of data concerning:

- (1) a practitioner practicing a particular specialty or field of health care;
- (2) a dispenser doing business in a particular location; or
- (3) a recipient;

that indicates dispensing or receiving of controlled substances outside norms for dispensing or receiving controlled substances established by the board under this chapter.

As added by P.L.163-1994, SEC.5. Amended by P.L.42-2011, SEC.75.

IC 35-48-7-5

"Identification number" defined

Sec. 5. As used in this chapter, "identification number" refers to the following:

- (1) The unique number contained on any of the following:
 - (A) A valid driver's license of a recipient or a recipient's representative issued under Indiana law or the law of any other state.
 - (B) A recipient's or a recipient representative's valid military

identification card.

(C) A valid identification card of a recipient or a recipient's representative issued by:

- (i) the bureau of motor vehicles as described in IC 9-24-16-3; or
- (ii) any other state and that is similar to the identification card issued by the bureau of motor vehicles.

(D) If the recipient is an animal:

- (i) the valid driver's license issued under Indiana law or the law of any other state;
- (ii) the valid military identification card; or
- (iii) the valid identification card issued by the bureau of motor vehicles and described in IC 9-24-16-3 or a valid identification card of similar description that is issued by any other state;

of the animal's owner.

(2) The identification number or phrase designated by the central repository.

As added by P.L.163-1994, SEC.5. Amended by P.L.204-2005, SEC.22.

IC 35-48-7-5.2

"INSPECT" defined

Sec. 5.2. As used in this chapter, "INSPECT" means the Indiana scheduled prescription electronic collection and tracking program established by IC 25-1-13-4.

As added by P.L.65-2006, SEC.3.

IC 35-48-7-5.4

"Interoperability" defined

Sec. 5.4. As used in this chapter, "interoperability" refers to the INSPECT program electronically sharing reported information with another state concerning the dispensing of a controlled substance:

- (1) to a recipient who resides in the other state; or
- (2) prescribed by a practitioner whose principal place of business is located in another state.

As added by P.L.65-2006, SEC.4.

IC 35-48-7-5.6

"Patient" defined

Sec. 5.6. As used in this chapter, "patient" means an individual who has requested or received health care services from a provider for the examination, treatment, diagnosis, or prevention of a physical or mental condition.

As added by P.L.65-2006, SEC.5.

IC 35-48-7-5.8

"Practitioner" defined

Sec. 5.8. As used in this chapter, "practitioner" means a physician, dentist, veterinarian, podiatrist, nurse practitioner, scientific

investigator, pharmacist, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in the United States.
As added by P.L.65-2006, SEC.6.

IC 35-48-7-6

"Recipient" defined

Sec. 6. As used in this chapter, "recipient" means an individual for whom a controlled substance is dispensed.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-7

"Recipient representative" defined

Sec. 7. As used in this chapter, "recipient representative" means the individual to whom a controlled substance is dispensed if the recipient is either less than eighteen (18) years of age or unavailable to receive the controlled substance.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-7.5

"State" defined

Sec. 7.5. As used in this chapter, "state" means any state of the United States or the District of Columbia.

As added by P.L.65-2006, SEC.7.

IC 35-48-7-8

Repealed

(Repealed by P.L.3-2008, SEC.269.)

IC 35-48-7-8.1

Controlled substance prescription monitoring program; information; prescription forms; identification

Sec. 8.1. (a) The board shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the board under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the INSPECT program the following information:

- (A) The controlled substance recipient's name.
- (B) The controlled substance recipient's or the recipient representative's identification number or the identification number or phrase designated by the INSPECT program.
- (C) The controlled substance recipient's date of birth.
- (D) The national drug code number of the controlled substance dispensed.
- (E) The date the controlled substance is dispensed.
- (F) The quantity of the controlled substance dispensed.
- (G) The number of days of supply dispensed.

- (H) The dispenser's United States Drug Enforcement Agency registration number.
 - (I) The prescriber's United States Drug Enforcement Agency registration number.
 - (J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.
 - (K) Other data required by the board.
- (2) The information required to be transmitted under this section must be transmitted as follows:
- (A) Before July 1, 2015, not more than seven (7) days after the date on which a controlled substance is dispensed.
 - (B) Beginning July 1, 2015, and until December 31, 2015, not more than three (3) days after the date on which a controlled substance is dispensed.
 - (C) Beginning January 1, 2016, and thereafter, not more than twenty-four (24) hours after the date on which a controlled substance is dispensed.
- (3) A dispenser shall transmit the information required under this section by:
- (A) uploading to the INSPECT web site;
 - (B) a computer diskette; or
 - (C) a CD-ROM disk;
- that meets specifications prescribed by the board.
- (4) The board may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the board may not apply such a requirement to prescriptions filled at a pharmacy with a Category II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The board may not require multiple copy prescription forms for any prescriptions written. The board may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be approved by the Indiana board of pharmacy established by IC 25-26-13-3.
- (5) The costs of the program.

(b) This subsection applies only to a retail pharmacy. A pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance may not dispense a controlled substance to a person who is not personally known to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance unless the person taking possession of the controlled substance provides documented proof of the person's identification to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance.

As added by P.L.65-2006, SEC.9. Amended by P.L.182-2009(ss), SEC.399; P.L.84-2010, SEC.97; P.L.94-2010, SEC.13; P.L.42-2011, SEC.76; P.L.152-2012, SEC.14; P.L.131-2014, SEC.9.

IC 35-48-7-9

Repealed

(Repealed by P.L.65-2006, SEC.18.)

IC 35-48-7-10

Repealed

(Repealed by P.L.3-2008, SEC.269.)

IC 35-48-7-10.1

INSPECT program; designation; powers and duties; funding

Sec. 10.1. (a) The INSPECT program must do the following:

(1) Create a data base for information required to be transmitted under section 8.1 of this chapter in the form required under rules adopted by the board, including search capability for the following:

- (A) A controlled substance recipient's name.
- (B) A controlled substance recipient's or recipient representative's identification number.
- (C) A controlled substance recipient's date of birth.
- (D) The national drug code number of a controlled substance dispensed.
- (E) The dates a controlled substance is dispensed.
- (F) The quantities of a controlled substance dispensed.
- (G) The number of days of supply dispensed.
- (H) A dispenser's United States Drug Enforcement Agency registration number.
- (I) A prescriber's United States Drug Enforcement Agency registration number.
- (J) Whether a prescription was transmitted to the pharmacist orally or in writing.
- (K) A controlled substance recipient's method of payment for the controlled substance dispensed.

(2) Provide the board with continuing twenty-four (24) hour a day online access to the data base.

(3) Secure the information collected and the data base maintained against access by unauthorized persons.

(b) The board may execute a contract with a vendor designated by the board to perform any function associated with the administration of the INSPECT program.

(c) The INSPECT program may gather prescription data from the Medicaid retrospective drug utilization review (DUR) program established under IC 12-15-35.

(d) The board may accept and designate grants, public and private financial assistance, and licensure fees to provide funding for the INSPECT program.

As added by P.L.65-2006, SEC.11. Amended by P.L.84-2010, SEC.98.

IC 35-48-7-11

Repealed

(Repealed by P.L.3-2008, SEC.269.)

IC 35-48-7-11.1

Confidentiality

Sec. 11.1. (a) Information received by the INSPECT program under section 8.1 of this chapter is confidential.

(b) The board shall carry out a program to protect the confidentiality of the information described in subsection (a). The board may disclose the information to another person only under subsection (c), (d), or (g).

(c) The board may disclose confidential information described in subsection (a) to any person who is authorized to engage in receiving, processing, or storing the information.

(d) Except as provided in subsections (e) and (f), the board may release confidential information described in subsection (a) to the following persons:

(1) A member of the board or another governing body that licenses practitioners and is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance.

(2) An investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general, who is engaged in:

(A) an investigation;

(B) an adjudication; or

(C) a prosecution;

of a violation under any state or federal law that involves a controlled substance.

(3) A law enforcement officer who is an employee of:

(A) a local, state, or federal law enforcement agency; or

(B) an entity that regulates controlled substances or enforces controlled substances rules or laws in another state;

that is certified to receive controlled substance prescription drug information from the INSPECT program.

(4) A practitioner or practitioner's agent certified to receive information from the INSPECT program.

(5) A controlled substance monitoring program in another state with which Indiana has established an interoperability agreement.

(6) The state toxicologist.

(7) A certified representative of the Medicaid retrospective and prospective drug utilization review program.

(8) A substance abuse assistance program for a licensed health care provider who:

(A) has prescriptive authority under IC 25; and

(B) is participating in the assistance program.

(e) Information provided to an individual under:

(1) subsection (d)(3) is limited to information:

(A) concerning an individual or proceeding involving the

unlawful diversion or misuse of a schedule II, III, IV, or V controlled substance; and

(B) that will assist in an investigation or proceeding; and

(2) subsection (d)(4) may be released only for the purpose of:

(A) providing medical or pharmaceutical treatment; or

(B) evaluating the need for providing medical or pharmaceutical treatment to a patient.

(f) Before the board releases confidential information under subsection (d), the applicant must be approved by the INSPECT program in a manner prescribed by the board.

(g) The board may release to:

(1) a member of the board or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive controlled substance prescription drug information; and

(B) approved by the board to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

(h) The information described in subsection (g) may not be released until it has been reviewed by:

(1) a member of the board who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data; or

(2) the board's designee;

and until that member or the designee has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (i).

(i) An investigator or a law enforcement officer receiving confidential information under subsection (c), (d), or (g) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:

(1) A proceeding under IC 16-42-20.

(2) A proceeding under any state or federal law that involves a controlled substance.

(3) A criminal proceeding or a proceeding in juvenile court that involves a controlled substance.

(j) The board may compile statistical reports from the information described in subsection (a). The reports must not include information that identifies any practitioner, ultimate user, or other person administering a controlled substance. Statistical reports compiled under this subsection are public records.

(k) Except as provided in IC 25-22.5-13, this section may not be

construed to require a practitioner to obtain information about a patient from the data base.

(l) A practitioner is immune from civil liability for an injury, death, or loss to a person solely due to a practitioner seeking or not seeking information from the INSPECT program. The civil immunity described in this subsection does not extend to a practitioner if the practitioner receives information directly from the INSPECT program and then negligently misuses this information. This subsection does not apply to an act or omission that is a result of gross negligence or intentional misconduct.

(m) The board may review the records of the INSPECT program. If the board determines that a violation of the law may have occurred, the board shall notify the appropriate law enforcement agency or the relevant government body responsible for the licensure, regulation, or discipline of practitioners authorized by law to prescribe controlled substances.

(n) A practitioner who in good faith discloses information based on a report from the INSPECT program to a law enforcement agency is immune from criminal or civil liability. A practitioner that discloses information to a law enforcement agency under this subsection is presumed to have acted in good faith.

As added by P.L.65-2006, SEC.13. Amended by P.L.84-2010, SEC.99; P.L.131-2014, SEC.10.

IC 35-48-7-11.5

Dissemination of exception reports

Sec. 11.5. (a) Each board of a health care provider that prescribes or dispenses prescription drugs shall do the following:

(1) Establish prescribing norms and dispensing guidelines for the unsolicited dissemination of exception reports under section 11.1(d) of this chapter.

(2) Provide the information determined in subdivision (1) to the board.

(b) The exception reports that are disseminated based on the prescribing norms and dispensing guidelines established under subsection (a) must comply with the following requirements:

(1) A report of prescriptive activity of a practitioner to the practitioner's professional licensing board designee when the practitioner deviates from the dispensing guidelines or the prescribing norms for the prescribing of a controlled substance within a particular drug class.

(2) A reporting of recipient activity to the practitioners who prescribed or dispensed the controlled substance when the recipient deviates from the dispensing guidelines of a controlled substance within a particular drug class.

(c) The board designee may, at the designee's discretion, forward the exception report under subsection (b)(2) to only the following for purposes of an investigation:

(1) A law enforcement agency.

(2) The attorney general.

As added by P.L.84-2010, SEC.100.

IC 35-48-7-12

Repealed

(Repealed by P.L.3-2008, SEC.269.)

IC 35-48-7-12.1

Rules to implement chapter

Sec. 12.1. (a) The board shall adopt rules under IC 4-22-2 to implement this chapter, including the following:

- (1) Information collection and retrieval procedures for the INSPECT program, including the controlled substances to be included in the program required under section 8.1 of this chapter.
- (2) Design for the creation of the data base required under section 10.1 of this chapter.
- (3) Requirements for the development and installation of online electronic access by the board to information collected by the INSPECT program.
- (4) Identification of emergency situations or other circumstances in which a practitioner may prescribe, dispense, and administer a prescription drug specified in section 8.1 of this chapter without a written prescription or on a form other than a form specified in section 8.1(a)(4) of this chapter.
- (5) Requirements for a practitioner providing treatment for a patient at an opioid treatment program operating under IC 12-23-18 to check the INSPECT program:
 - (A) before initially prescribing a controlled substance to a patient; and
 - (B) periodically during the course of treatment that uses a controlled substance.

(b) The board may:

- (1) set standards for education courses for individuals authorized to use the INSPECT program;
- (2) identify treatment programs for individuals addicted to controlled substances monitored by the INSPECT program; and
- (3) work with impaired practitioner associations to provide intervention and treatment.

As added by P.L.65-2006, SEC.15. Amended by P.L.84-2010, SEC.101; P.L.42-2011, SEC.77; P.L.131-2014, SEC.11.

IC 35-48-7-13

Repealed

(Repealed by P.L.3-2008, SEC.269.)

IC 35-48-7-13.1

Controlled substances data fund; establishment

Sec. 13.1. (a) The controlled substances data fund is established to fund the administration of the INSPECT program. The fund shall be administered by the Indiana professional licensing agency.

(b) Expenses of administering the fund shall be paid from money in the fund. The fund consists of grants, public and private financial assistance, and the controlled substances registration fees imposed under rules adopted under IC 35-48-3-1.

(c) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested.

(d) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

As added by P.L.65-2006, SEC.17. Amended by P.L.114-2013, SEC.2; P.L.112-2014, SEC.39.

IC 35-48-7-14

Violations of chapter; misdemeanor offense

Sec. 14. A person who knowingly or intentionally violates this chapter commits a Class A misdemeanor.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-15

Repealed

(Repealed by P.L.214-2001, SEC.1.)

IC 35-48-7-16

Study and report on inclusion of prescription drugs in INSPECT

Sec. 16. (a) Before October 1, 2014, the Indiana professional licensing agency shall:

- (1) study the impact of including all prescription drugs in the INSPECT program; and
- (2) report the findings to the legislative council in an electronic format under IC 5-14-6.

(b) The study under subsection (a) must include the following:

- (1) The efficacy of including drugs other than controlled substances in the INSPECT program.
- (2) Recommended parameters for the inclusion of drugs other than controlled substances.
- (3) Analysis of any security concerns related to patient and provider privacy.
- (4) Technology requirements.
- (5) Regulatory impact analysis.
- (6) Fiscal impact analysis.

(c) The:

- (1) state department of health;
- (2) office of the secretary of family and social services;
- (3) department of homeland security; and
- (4) Indiana office of technology (IC 4-13.1-2);

shall assist the Indiana professional licensing agency with the study required by this section.

As added by P.L.131-2014, SEC.12.